REMARKS

The Office Action dated November 19, 2008 has been carefully considered. Claims 25, 32, 34, 35 and 37 have been amended. Claim 38 has been canceled. Claims 1-14, 20-22 and 24-37 are in this application.

Claim 38 was withdrawn as being directed to a non-elected invention. Claim 38 has been canceled. Applicants respectfully reserve the right to file a divisional application directed to the unelected claim.

Claim 33 is allowed.

Claims 32, 34, 35 and 37 were objected to as informal. Applicants have amended claims 32, 34, 35 and 37 to obviate the Examiner's objection.

The previously presented claims 1, 2, 4-10, 20-22, 24-31 and 36 were rejected under 35 U.S.C. § 103 as being obvious in view of U.S. Patent No. 6,648,911 to Sirhan et al. in combination with U.S. Patent No. 6,112,109 to D'Urso.

Sirhan et al. describe a method and device for treatment of a vulnerable tissue site, such as arterial and other aneurysms in the abdominal area or thoractic cavity. A tubular containment member is disposed around the exterior surface over a length of a weakened aortic wall of an aortic aneurysm to support the weakened aortic wall. As noted by the Examiner in the Office Action, Sirhan et al. do not disclose that the stent is customized or pre-formed.

D'Urso teaches constructive modeling of articles including prostheses. D'Urso discloses constructing a plurality of two dimensional cross-section images from CT scan data and using the two dimensional data to create three dimensional coordinate data sets for the articles to be modeled. The model can be used to construct the prostheses.

In contrast to the invention defined by the present claims, D'Urso does not teach or suggest a stent being customized to a patient and pre-formed having a size and shape which morphologically matches the morphological profile and contour of the ascending aorta. Further, D'Urso does not teach or suggest that the stent supports the exterior of the ascending aorta in substantially full contact therewith. The Examiner stated that it would be obvious to combine the methods of D'Urso to create the stent of Sirhan et al. Applicants respectfully disagree. D'Urso teaches that a prosthetic implant is used to replace an aortic junction. (Col 9, lines 35-38).

However, at col. 1, lines 19-31, Sirhan et al. teach against treatment using a prostheses because it "causes considerable trauma, results in high mortality and morbidity and, even when completely successful, requires a lengthy recuperation period." Thus, Sirhan et al. teach away from use of a prostheses. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Applicant. *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed.Cir. 1994).; see *KSR*, 127 S.Ct. at 1739-40 (explaining that when the prior art teaches away from a combination, that combination is more likely to be non-obvious). Accordingly, one of ordinary skill in the art would not look to D'Urso for combination with Sirhan et al. because Sirhan et al. teach away from the teachings of D'Urso. Moreover, D'Urso only teaches the use of a model to construct a prostheses and Sirhan et al. only teach placement of a non-customized stent. Neither of the references alone or in combination teach that the stent is customized to a patient and pre-formed to morphologically match the morphological profile and contour of the ascending aorta. Thus, the invention defined by the present claims is not obvious in view of Sirhan et al. alone or in combination with D'Urso.

Dependent claims 2, 4, 6-10, 20-22, 24 and 26 which are dependent on claim 1 are believed to be allowable for the same reasons that claim 1 is allowable.

With regard to claim 25, neither Sirhan et al. nor D'Urso teach or suggest that a stent is formed of a heat shrink plastics material to produce the morphological fit. The use of this material in the present invention provides a dense structure that is not taught or suggested in Sirhan et al. Rather, Sirhan et al. teach strands of material which can be formed of a thermoplastic wound in a helical fashion which strands do not produce a morphological fit. Accordingly, claim 25 is not obvious in view of Sirhan et al. alone or in combination with D'Urso.

Claims 3, 11, and 12 were rejected under 35 U.S.C. § 103 as obvious in view of Sirhan et al. in combination with U.S. Patent No. 6,197,050 to Eno et al.

Eno et al. describe a transmyocardial implant for establishing blood through a myocardium between a heart chamber and a lumen of a coronary vessel. The implant includes a hollow conduit having a first portion and a second portion. The first portion has an axial

dimension aligned with an axis of the vessel. The second portion is sized to extend from the vessel through the myocardium into the heart chamber. A collar surrounds an exterior of the artery overlying the first portion and the first open end. The collar can have thickened and thinned portions.

In contrast to the invention defined by the present claims, Eno et al. do not teach or suggest a stent being customized to a patient and pre-formed having a size and shape which morphologically matches the morphological profile and contour of the blood vessel. In Eno et al., the stent is not customized and pre-formed to be in morphological relationship with the blood vessel. The stent of Eno et al. imposes its own morphology on the blood vessel. Accordingly, Eno et al. do not cure the deficiencies of Sirhan et al. or D'Urso described above and the invention defined by the present claims is not obvious in view of Sirhan et al. and D'Urso in combination with Eno et al.

Claims 13 and 14 were rejected under 35 U.S.C. § 103 as obvious in view of Sirhan et al. in combination with U.S. Patent No. 6,554,856 to Doorly et al.

Doorly et al. disclose a stent for supporting part of a blood vessel. The stent includes a supporting portion around which or with which an associate graft can be placed.

In contrast to the invention defined by the present claims, Doorly et al. do not teach or suggest a stent having a size and shape which morphologically matches the morphological profile of the ascending aorta and that the stent supports the exterior of the ascending aorta in substantially full contact therewith. Rather, Doorly et al. is directed to a stent for supporting a blood vessel having a non-planar curved form. Doorly et al. imposes its own morphology on the blood vessel. Accordingly, Doorly et al. do not cure the deficiencies of Sirhan et al. and D'Urso described above and the invention defined by the present claims is not obvious in view of Sirhan et al. and D'Urso in combination with Doorly et al.

Previously presented claim 34 was rejected under 35 U.S.C. § 103 as obvious in view of D'Urso in combination with U.S. Patent Application Publication No. 2006/0036311 to Nakayama et al.

Nakayama et al. teach a tubular stent matrix of which diameter is extendable and a flexible polymer layer covers the stent matrix. The polymer layer formed is perforated by excimer laser.

In contrast to the invention defined by the present claims, Nakayama et al. do not teach or suggest the method of manufacturing a stent by the steps of producing a 3D computerised model from a scanned image of the ascending aorta to which the stent is in practice to be applied, and rapid prototyping the computerised 3D model in an appropriate material to provide the stent or a mould for the stent or a precursor thereof for morphologically matching the ascending aorta and the stent is formed of polymeric material produced to conform morphologically to the 3D image in the form of a thin shell, the shell is mounted in a computer numerically controlled machine having multiple axes control. Accordingly, Nakayama et al. do not cure the deficiencies of D'Urso noted above and the invention defined by the present claims is not obvious in view of Nakayama et al.

Previously presented claims 32 and 35 were rejected under 35 U.S.C. § 103 as obvious in view of D'Urso in combination with U.S. Patent No. 6,899,728 to Phillips et al. D'Urso does not teach or suggest a method of manufacturing a stent for morphologically fitting a blood vessel of a patient to conform morphologically to the contour of the blood vessel by providing a stent to support its exterior in essentially full contact therewith, as described above.

Phillips et al. teach a reinforced graft formed on a flexible sheet of graft material which is sewn to a reinforcing wire. Sewing of the wire is carried out while the sheet is substantially planar by embroidery machines.

There is no teaching or suggestion in Phillips et al. of morphologically fitting a blood vessel of a patient to conform morphologically to the contour of the blood vessel by providing a sleeve to support its exterior in essentially full contact therewith. Further, Phillips et al. do not teach or suggest embroidery of a 3D image onto a 2D substrate element. Applicants submit it is only in hindsight that the Examiner can combine Phillips et al. directed to a reinforced graft with D'Urso directed to constructive modeling of articles. Further, even if the references could be combined, the teachings of the references do not disclose or suggest the invention defined by the present claims.

In view of the foregoing, Applicants submit that all pending claims are in condition for allowance and request that all claims be allowed. The Examiner is invited to contact the undersigned should he believe that this would expedite prosecution of this application. It is believed that no fee is required. The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2165.

Respectfully submitted,

Dated: May 18, 2009

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